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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/419,461	10/15/99	KHALIL	6351.US.P2

EXAMINER	
KREMER, M	
ART UNIT	PAPER NUMBER
3736	4

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/419,461	KHALIL ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-52 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 51 is objected to because of the following informalities. For claim 51, the word "is" is used twice in a row. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 51 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 51 recites the limitation "said disease state" in which there is insufficient antecedent basis.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 7-16, 19-21, 25-34, 37-39, 43-46, and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, and 35-36 of U.S. copending Application No. 09/080,470 to Khalil et al. in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (cited by Applicant). This is a provisional obviousness-type double patenting rejection. Claim 13 of Khalil et al. discloses a method of measuring one or more parameters of a body part by setting the body to one temperature (step a), taking an optical measurement of light which has been reflected, scattered, absorbed, or emitted (step b), determining an optical property (step c), setting the body to another temperature (step d), determining an optical property (step e), and analyzing the optical properties to determine one parameter (step f). Khalil et al. does not disclose that the first temperature corresponds to a first depth in the body part and the second temperature corresponds to a second depth in the body part. Laufer et al. discloses on page 2488 that there is a decrease in the scattering coefficient for the subdermis and an increase for the dermis with temperature. It is implied that at different temperatures, different layers are being measured in relation to reflected measurements since the average sampling depth of the measurements is shifting. Functionally, the method of Khalil performs this operation since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Khalil

to include the fact that a temperature corresponds to the depth in a body part as disclosed by Laufer et al. since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Claims 1-3, 11-12, 14-16, 19-21, 29-30, and 32-34 are rejected over claim 13 of Khalil et al. Claims 13 and 31 are rejected over claims 14-15 and 46-47 of Khalil et al. Claims 37-39, 46-47, and 49 are rejected over claim 33 of Khalil et al. Claim 44 is rejected over claim 35 of Khalil et al. Claim 45 is rejected over claim 36 of Khalil et al. In regard to claims 7-8, 25-26, and 43, Laufer et al. performed the diffuse reflectance measurements at four different temperatures : 25, 30, 35, and 40 degree Celsius as stated on page 2479 of Laufer et al. In regard to claims 9-10 and 27-28, Laufer et al. shows in Figs. 2-3 that the wavelengths of interest are between 650 and 1000 nm.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 6-21, 24-39, 42-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (cited by Applicant). Mills discloses a method and apparatus for

monitoring blood parameters which makes use of measurements of the behavior of substances which are affected by temperature as stated column 1, lines 16-25. In column 9, lines 1-33, Mills teaches that to generate data, the temperature induction means is used to bring the finger (or tubing or other space of interest) to a known temperature, light of known wavelength and intensity is emitted on the surface of interest. Detection of the light signal at a distinct point (normally opposing surface) is made and the relative absorbance and extinction of the signal is calculated. The process is repeated at the next chosen wavelength, while still at the same predetermined temperature. Once the desired number of wavelengths has been examined, the temperature induction means would bring the volume to a predetermined second temperature, and the data collection of steps would be repeated. At the completion of measurements and determinations for this second temperature, the temperature induction means will bring the space to a third predetermined temperature, and the measurements and determinations repeated. This process would be continued until the desired range of temperatures has been sampled. Mills does not disclose that the first temperature corresponds to a first depth in the body part and the second temperature corresponds to a second depth in the body part. Laufer et al. presents a study on the influence of temperature on the optical properties of human dermis and subdermis. Laufer et al. discloses on page 2488 that there is a decrease in the scattering coefficient for the subdermis and an increase for the dermis with temperature. This implies that at different temperatures, different layers are being measured in relation to reflected measurements since the average sampling depth of the

measurements is shifting. Functionally, the method of Mills performs this operation since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mills to include the fact that a temperature corresponds to the depth in a body part as disclosed by Laufer et al. since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Mills discloses in column 14, line 66 to column 15, line 9 that blood samples can be taken, stored and analyzed at a later date. The blood samples implies that the locations of measurements do not have to be attached to the human body at the time of measurement. This implies that other locations can be examined apart from the body such as the method of examining tissue samples. Laufer et al. shows that reflective measurements can be performed on tissue samples separated from the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mills to include the method of examination of separated tissue as disclosed by Laufer et al. since the method of Mills implies samples can be separated from the body and the method of Laufer et al. allows samples to be taken, stored, and analyzed at a later date.

In regard to claims 3, 21, and 39, Mills teaches in column 8, lines 1-3 that reflectance spectrophotometry can be used. In regard to claims 7-8, 25-26, and 43, Laufer et al. performed the diffuse reflectance measurements at four different

temperatures: 25, 30, 35, and 40 degree Celsius as stated on page 2479 of Laufer et al. In regard to claims 9-10, 27-28, and 44-45, Laufer et al. shows in Figs. 2-3 that the wavelengths of interest are between 650 and 1000 nm. In regard to claims 11-12, 29-30, and 46-47, Mills teaches that glucose and hemoglobin can be measured as stated in column 13, lines 31-35. In regard to claims 13, 31, and 48, Laufer et al. teaches on page 2479 that absorption coefficient and transport scattering coefficients were determined for the reflection measurements. In regard to claims 14 and 32, Laufer et al. performs experiments on tissue specimens from the abdomen of three patients as stated on page 2480 of Laufer et al. In regard to claims 15-16, 33-34, and 49, Mills performs experiments on the finger as shown in Fig. 6 of Mills. In regard to claims 17-18, 35-36, and 50-51, Mills states in column 14, lines 11-25 that the invention can be used to determine sickle cell disease, certain cancers, and other diseases or conditions which are distinguished by markers in blood. In column 8, line 31, Mills teaches glucose can be measured which aids in determining diabetes.

8. Claims 4-5, 22-23, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (cited by Applicant) as applied to claims 1 and 19 in view of U.S. Patent 5,782,755 to Chance et al. (1998). The combination does not teach that the optical measurement is a spatially resolved diffuse reflectance measurement. Chance et al. (1998) discloses an invention which monitors one or more solutes in a biological system

comprising the steps of: delivering light into a biological system containing one or more solutes, detecting at least first and second portions of the delivered light, both portions having traveled through the biological system along one or more paths characterized by different path lengths, and comparing the first and second portions of the delivered light to monitor a concentration of one or more of the solutes in the biological system as stated in column 1, lines 45-62 of Chance et al. (1998). Column 3, lines 6-19 of Chance et al teaches that approximation of the exact solution for the spatially resolved reflectance at separations larger than 2.5 cm provides a linear relationship between the separation and absorbance variation with respect to a reference sample. Slope and intercept of this straight line are functions of the absorption and scattering coefficients of the measured sample. Using this technique, high measurement sensitivities for solute concentrations in a biological system can be achieved. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include spacially resolved reflectance as disclosed by Chance et al. (1998) since high measurement sensitivities for solute concentrations in a biological system can be achieved. In regard to claims 5, 23, and 41, Chance et al. (1998) states that frequency domain measurement can be employed as stated in column 20, lines 1-20.

9. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (cited by

Applicant) as applied to claim 37 in view of U.S. Patent 5,873,821 to Chance et al. (1999). The combination does not teach the use of an endoscope. Chance et al. (1999) discloses an oximeter that determines the oxygenation state of localized body tissue which includes at least a pair of spaced apart light sources and a pair of wave length-specific light detectors (e.g., photodetectors) as stated in column 3, lines 40-53. Each light source transmits specific wavelengths toward a tissue of interest and each detector receives photons of the respective specific wavelength that have originated from each light source and scattered from the localized tissue. Chance et al. (1999) further teaches that the oximeter can be disposed on an endoscope, catheter or guidewire or the like for insertion via a body passage to internal tissue as stated in column 6, lines 48-54. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include an endoscope as disclosed by Chance et al. (1999) since an endoscope would allow examination of internal tissue.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,161,028 to Braig et al. (2000) discloses a method of determining the analyte concentration of a test sample by inducing a temperature gradient in the test sample and infrared radiation detectors measure radiation at selected analyte absorbance peak and reference wavelengths. U.S. Patent 6,198,949 to Braig et al. (2001) discloses a solid-state spectrometer for the non-invasive

generation and capture of thermal gradient spectra from human or animal tissue. The spectrometer includes an infrared transmissive thermal mass window for inducing a transient temperature gradient in the tissue, a cooling element cooling the thermal mass window, an infrared sensor for detecting infrared emissions emanating from the tissue as the transient temperature gradient progresses into the tissue and for providing output signals proportional to the detected infrared emissions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Examiner
Art Unit 3736
April 20, 2001

ERIC F. WINAKUR
PRIMARY EXAMINER